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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,384	10/22/2003	Stephen P. Oliver	HME/7477.0017	8786

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HOWARD EISENBERG, ESQ.
2206 APPLEWOOD COURT
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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,384	OLIVER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction / Species Election

1) Claims 1-45 are under prosecution.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 11-14, drawn to a polypeptide comprising SEQ ID NO: 4, classified in class 530, subclass 350

II. Claims 6-10, drawn to a polypeptide comprising SEQ ID NO: 2 or SEQ ID NO: 15, classified in class 530, subclass 350

III. Claims 15-17, drawn to a nucleic acid that hybridizes to the complement of the nucleotide sequence of SEQ ID NO: 5, classified in class 536, subclass 23.7

IV. Claims 18-26, drawn to a nucleic acid that hybridizes to the complement of SEQ ID NO: 1 or SEQ ID NO: 3, classified in class 536, subclass 23.7

V. Claims 27-35, drawn to a polypeptide encoded by the nucleic acid of claims 18-26, classified in class 530, subclass 350/300

VI. Claims 36-39, drawn to an antibody that selectively binds to a polypeptide of SEQ ID NO: 4, classified in class 530, subclass 139.1

VII. Claims 40-43, drawn to an antibody that selectively binds to a polypeptide of SEQ ID NO: 1 or SEQ ID NO: 3, classified in class 530, subclass 139.1

VIII. Claims 44 and 45, drawn to a nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID N: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, and SEQ ID NO: 11, classified in class 536, subclass 24.33

3) Inventions I-VIII are distinct from one another. These inventions are directed to eight distinct products, which differ from one another in their structure, composition, biologic function, and immunospecificity. A polypeptide is a single chain molecule, which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. Therefore the two are structurally distinct molecules. An antibody is a glycoprotein and includes for example IgG, which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Any relationship between a nucleic acid molecule and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to

the primary amino acid sequence of the encoded polypeptide. While the polypeptides of inventions I and V can be made by methods of using the nucleic acids of inventions II and III, these polypeptides can also be made by biochemical or synthetic means. For instance, the polypeptides can be produced by chemical synthesis without the use of nucleic acid molecules. The nucleic acid molecules of inventions III, IV and VIII will not encode antibodies of inventions VI and VII. The polypeptides, nucleic acids, and antibodies are structurally distinct molecules, belong to different classes, and require separate and non-coextensive searches.

Although the polypeptides of inventions I, II and V belong to the same class, each polypeptide has a structure that is distinct from the other, requiring a separate or individual sequence or oligomeric search.

Similarly, the nucleic acids of inventions III, IV and VIII belong to the same class, each nucleic acid has a structure that is distinct from the other, requiring a separate or individual sequence or oligonucleotide search.

Likewise, the antibodies of inventions VI and VIII belong to the same class, each polypeptide to which the antibody is specific to has a structure that is distinct from the other polypeptide, requiring a separate or individual sequence search for the polypeptide.

4) In the instant case, a search of polypeptides, nucleic acid molecules, and antibodies are not coextensive because these products have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate amino acid and DNA databases. There is also search burden with regard to the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest, there may be journal articles devoted solely to polypeptides, which would not have described the nucleic acid molecules. Similarly, there may have been 'classical' genetics papers which had no knowledge of the polypeptides but spoke to the gene. Furthermore, the antibodies to the polypeptides may be known even if the polypeptides are novel. In addition, the technical literature search for the polypeptides and the antibodies are not coextensive, e.g., antibodies may be characterized in the technical literature prior to the discovery of, or sequencing of the polypeptides to which they are specific. Searching inventions I-VIII therefore would impose a serious search burden.

Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art as shown by their different classification/subclassification and divergent subject matter, and because the search required for each group is not required for the other groups since each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5) Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

6) Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

7) This application contains claims directed to the following patentably distinct species of the claimed invention. Applicants are required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(A) If invention II is elected, Applicants must elect one of the following polypeptide species in claims 6-10: (a) SEQ ID NO: 2; and (b) SEQ ID NO: 15.

(B) If invention IV is elected, Applicants must elect one of the following nucleic acid species which hybridizes to: (a) SEQ ID NO: 1 (claims 18 and 21); (b) SEQ ID NO: 3 (claims 18 and 24; (c) nucleotide sequence of nucleotides 311-2836 and 317 to 2836 of SEQ ID NO: 1 (claims 19, 20, 22 and 23); and (d) nucleotide sequence of nucleotides 283 to 2808 and 289 to 2808 of SEQ ID NO: 3 (claims 19, 20, 25 and 26).

(C) If invention V is elected, Applicants must elect one of the following polypeptide species: (a) a polypeptide encoded by a nucleic acid that hybridizes to SEQ ID NO: 1 (claims 27 and 30); (b) a polypeptide encoded by a nucleic acid that hybridizes to SEQ ID NO: 3 (claims 27 and 33); (c) a polypeptide encoded by a nucleic acid that hybridizes to nucleotide sequence of nucleotides 311-2836 and 317 to 2836 of SEQ ID NO: 1 (claims 28, 29, 31 and 32); and (d) a

polypeptide encoded by a nucleic acid that hybridizes to nucleotides 289-2808 and 283 to 2808 of SEQ ID NO: 3 (claims 28, 29, 34 and 35).

(D) If invention VII is elected, Applicants must elect one of the following antibody species in claims 40-43 having specificity to: (a) SEQ ID NO: 1; and (b) SEQ ID NO: 3.

(E) If invention VII is elected, Applicants must elect one of the following nucleic acid species in claims 44 and 45: (a) SEQ ID NO: 6; (b) SEQ ID NO: 7; (c) SEQ ID NO: 8; (d) SEQ ID NO: 9; (e) SEQ ID NO: 10; and (f) SEQ ID NO: 11.

Each of the species identified above requires a separate and individual structure search.

8) Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the

Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

S. DEVI, PH.D.
PRIMARY EXAMINER

September, 2006